



4th Meeting of The Member State Sub-Group on Joint Clinical Assessment (JCA)

5 October 2023, Hybrid Meeting

Summary Minutes

The fourth meeting of the Member State Sub-Group on Joint Clinical Assessment (JCA) set up by Regulation (EU) 2021/2282 was held on 5 October 2023 in hybrid format. Representatives from 24 Member States, as well as Norway in observer capacity, attended the meeting in presence or online.

The meeting was chaired by Paul de Boissieu (France), and co-chaired by Anne Willemsen (Netherlands).

The meeting covered the following points:

1) Opening of the meeting

The Chair welcomed the participants. The agenda of the meeting was approved with no changes.

Minutes from the third meeting of the JCA sub-group were approved with no changes.

2) Conflict of Interest

The Chair informed that the Commission had not identified any relevant Conflict-of-Interest for the purpose of this meeting. The Chair asked for any updates of the Declarations of Interest relevant for this meeting and none were received.

3) Feedback from recent relevant meetings

The Chair presented a summary of the 5th HTACG meeting held on 25 September, which included the discussion on timelines for joint work on Medical Devices, the timing of the EHT annual report scope, SOPs for sub-groups, and updates to the work programme 2023-24.

The Chair informed that the EUnetHTA 21¹ Service Contract finished on 16/09/2023 ending a very long period of joint voluntary work on HTA. The deliverables of the service contract are key inputs to develop the procedures and guidelines for the HTA Regulation.

The Chair reported on the 1st HTA Committee meeting on 15/09/2023, where concepts around the Implementing Act on JCA for medicinal products were discussed. The next meeting will be held on 20/10/2023 to discuss the draft Implementing Act on JCA for Medicinal Products and its Annexes.

4) Discussion of review documents

The Co-chair presented the Standard Operational Procedures (SOP) for the HTACG sub-groups which was circulated to all sub-group members and HTACG members in advance of the HTACG meeting. The

¹ <https://www.eunetha.eu/jointhtawork/>

comments received from 16 MS were presented summarised in five categories: to ensure the applicability for Medical Devices documents, to clarify scope of review, timelines and accelerated versus full procedure, to clarify the scope of the current SOP as interim, clarifications on the terminology of assessor and co-assessor, and finally to discuss and clarify with the HTA Secretariat the logistics of the subgroups work. As during the 2nd JCA subgroup meeting on May 23rd members agreed to organise working groups. A process flow will be added to the SOP, to clarify the steps.

5) Discussion with EHT SG Chair and co-Chair on JCA SG expectations of annual report

The Chair of the Emerging Health Technologies (EHT) sub-group introduced the objectives of the reports on horizon scanning for the next year and asked the JCA sub-group a number of issues related to the information expected and the specific health technologies to prioritise.

The discussion which followed raised several elements for the consideration of the EHT sub-group for the annual report. Short term expectation are ATMP and oncology medicinal products in 2025.

6) Early reflection on full time equivalent required for JCA production

The Chair announced to the sub-group that a survey would be launched in October, on the available resources for joint work on JCAs for 2025 in both configurations. The Chair and Co-chair explained how to fill in the survey and provided some examples of full-time equivalents from real MS calculations and EUnetHTA experiences.

7) PICO webinar

The Co-chair informed about the MPG and JCA sub-groups joint information webinar on the Scoping Process, scheduled for next Tuesday 10 October. The objectives are to provide details on the consolidation process and illustrate it by an example.

8) Work programme and upcoming review

The Chair reviewed the current and upcoming tasks in the work programme. Specifically, the SOP review, the Scoping Process review, guidance on the appointment of assessor and co-assessor and next year review of the procedural steps and timeframe for JCA.

9) IT platform

The Commission informed on the IT infrastructure for the HTACG joint work, as well as on the latest developments of the HTA-IT-Platform, which went live on 04/10/2023 with an Introductory and Training online session. A second session is planned for the end of October. Feedback from users is needed to further develop and enhance the working environment.

Finally, the Commission performed a live demonstration of the different elements/groups that compose the HTA-IT-Platform and the possibilities for current operational joint work.

Conclusion

The Chairs thanked all participants and summarised the main points for action: the review of the scoping guidance (October), the survey on FTE for completing JCAs (October) and volunteers to develop specific procedures and guidelines.

The next JCA sub-group meeting will take place on **10 November 2023**, in **virtual format**, from **10:00 to 13:00 h. CET**.

END.